

Remarks/Arguments:

Introduction

The specification has been amended to correct several minor typographical errors. Entry of these amendments is respectfully requested.

Claims 1, 3-11, 13-17, and 19-26 are pending. The independent claims 1, 8 and 17, have been amended to include the subject matter of dependent claims 2, 12 and 18, respectively. Accordingly, claims 2, 12 and 18 have been canceled. Moreover, claims 3, 5, 13, 19, 20 and 26 have been amended for antecedent basis consistent with the amendments to the independent claims.

Summary of the Present Invention

The invention as presently defined by independent Claim 1 is directed to a method of making a tubular stent/graft assembly. The inventive method of Claim 1 comprises the steps of (i) forming a substantially planar strip and wire assembly comprising first and second essentially flat, planar graft strips formable into a graft and essentially flat, planar stent wire formable into a radially adjustable stent, wherein said wire is positioned between said first and second graft strips and also positioned lengthwise along the length of said planar strip and further wherein said graft strips are formed by extruding, casting or molding polymeric material; and (ii) helically winding said substantially planar strip and wire assembly to form said tubular stent/graft assembly.

The invention as presently defined by independent Claim 8 is directed to a method of making a stent/graft assembly. The inventive method of Claim 8 comprises the steps of forming a substantially planar graft and stent material assembly comprising first and second essentially flat, planar graft strips and essentially flat, planar stent material, wherein said graft

strips are formed by extruding, casting or molding polymeric material, positioning said planar stent material between said first and second planar graft strips; and winding said substantially planar graft and stent assembly to form said stent/graft assembly.

The invention as presently defined by independent Claim 17 is directed to a method of making a tubular stent/graft assembly. The inventive method of Claim 17 comprises the steps of (i) forming a substantially planar strip and stent assembly comprising first and second essentially flat, planar graft strips formable into a graft and an essentially flat, planar stent formable into a radially adjustable stent, wherein said planar stent is positioned between said first and second planar graft strips and positioned along the length of said planar strips and further wherein said graft strips are formed by extruding, casting or molding polymeric material; and (ii) helically winding said substantially planar strip and stent assembly to form said tubular stent/graft assembly.

Thus, the independent claims of the present invention are directed to, *inter alia*, (1) firstly forming a planar stent-graft assembly strip comprising a planar stent positioned between two planar graft strips and then secondly helically winding the assembly strip to form a tubular stent-graft. The graft strips are of a nontextile construction.

Section 103 Rejections

Claims 1, 5, 6, 8-11, 14, 16, 17, 20, 21, 23, 24 and 26 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,824,040 to Cox et al. (hereinafter "Cox") in view of any one of U.S. Patent No. 6,488,701 to Nolting et al (hereinafter "Nolting"), U.S. Patent No. 6,143,022 to Shull et al (hereinafter "Shull") or U.S. Patent No. 5,527,353 to Schmitt (hereinafter "Schmitt"), either combined alone or optionally further taken with any one of U.S. Patent No. 5,226,913 to Pinchuk (hereinafter "Pinchuk

'913"), U.S. Patent No. 5,163,958 to Pinchuk (hereinafter "Pinchuk '958") or U.S. Patent No. 5,092,87 to Pinchuk (hereinafter "Pinchuk '877"). Applicant respectfully traverses.

In brief, the Examiner alleges that one of ordinary skill in the art would arrive at the present invention, as follows:

It should be noted that the reference to Cox et al suggested the generic concept defined in the claim, namely the associated of a planar strip of material with a wire assembly wherein the planar strip portion formed the graft material and the planar wire assembly formed the stent assembly. (Final Office Action dated Feb. 15, 2005, page 3, lines 3-6)

[I]t is agreed that each one of the references to Nolting et al, Shull et al, or Schmitt suggested that one skilled in the art would have formed the stent graft assembly in a different manner from that defined in the claims.... (Final Office Action dated Feb. 15, 2005, page 3, lines 14-16)

The applicant is advised that one is not ignoring the various processing steps performed by Nolting, Shull or Schmitt, rather these process steps need not be directly considered in the question of obviousness. One skilled in the art would have understood that the processing of Cox as disclosed would have been a suitable manner useful for forming the stent graft assembly. The question to be answered here is would it have been obvious to employ the specific strip graft material as claimed.... To resolve this question, the references to Nolting, Schmitt and Shull were all cited to expressly show that those skilled in the art at the time of the invention was made would have known to employ a ptfe material in the form of a strip of material.... (Final Office action dated Feb 15, 2005, page 4, line 15, to page 5, line 3)

[T]o form a stent component which was substantially planar was known to those of ordinary skill in the art. ... [N]one of Pinchuk '913, Pinchuk '958, or Pinchuk '877 expressly state the associate of their stents with a graft material.... (Final Office action dated Feb 15, 2005, page 5, line 21, to page 6, line 2)

Except for the express acknowledgement by the Examiner that Nolting, Shull and Schmitt fail to teach or suggest the process steps of the present invention and that the Pinchuk patents fail to teach or suggest stent-grafts, Applicant respectfully traverses.

Claims 1-24 and 26 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cox in view of any one of Nolting, Shull or Schmitt, either combined alone or optionally further taken with any one of Pinchuk '913, Pinchuk '958 or Pinchuk '877, further taken with either one of U.S. Patent No. 5,928,279 to Shannon et al. (hereinafter "Shannon") or U.S. Patent No. 6,517,571 to Brauker et al. (hereinafter "Brauker").

In brief, the Examiner alleges that one of ordinary skill in the art would arrive at the present invention by using Shannon and Brauker, as follows:

[The Shannon and Brauker] references were not cited for the specific processing [steps, but] were cited to show the specific material utilized to make a stent graft assembly and to further suggest that the ordinary artisan would have embedded the stent component between two graft components.... (Final Office Action dated Feb. 15, 2005, page 7, lines 4-11)

Applicant respectfully traverses on the basis that the Examiner has failed to make a *prima facie* case of obviousness, in view of the current amended claims.

Claim 25 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cox in view of any one of Nolting, Shull or Schmitt, either combined alone or optionally further taken with any one of Pinchuk '913, Pinchuk '958 or Pinchuk '877, in further view of U.S. Patent No. 6,361,637 to Martin et al. (hereinafter "Martin").

In brief, the Examiner alleges that one of ordinary skill in the art would arrive at the present invention by using Martin, as follows:

Application No.: 10/057,667
Amendment and Response dated April 7, 2005
Reply to Final Office Action of February 15, 2005
Docket No.: 760-12 DIV/RCE
Page 12

Regarding Martin, one skilled in the art would have selected a suitable material for the stent component and as such would have included nitinol as was a known compound useful for a stent component in a stent assembly. It would have been within the purview of the ordinary artisan to select suitable materials for use in the operation of Cox and such would have certainly included the use of a nitinol wire for the stent component as such nitinol was a convention material useful for a stent assembly. (Final Office Action dated Feb. 15, 2005, pages 8, lines 1-6)

Applicant respectfully traverses.

In traversing the Section 103 rejections the Applicant will (1) first describe the individual cited references and (2) will then describe the deficiencies of the various combinations of the cited references. The individual references are being firstly described to avoid repeating the details of the individual references in the later discussed Section 103 rejections. Thus, Applicant is not merely attacking the references individually as alleged by the Examiner at page 3, lines 16-18, of the subject Action, but discussing the totalality of the teachings of each reference so that their teachings as a whole will be considered.

Brief Description of the Individual References

Cox:

Cox is directed to a prosthesis having diamond shaped elements 73 sewn to a single strip of woven liner material 75 by being stitched to form a ribbon. (Cox, column 12, lines 19-24). The ribbon is then wound over a mandrel to form the prosthesis. (*Id.*; Fig. 5E.). The diamond shaped elements 73 are formed from at least two wires that are diagonally disposed in a zig-zag manner across the width of the liner material 75. (See, Cox, Fig. 5E). The liner material is described as a woven material made from polyester yarn or PTFE. (Cox, column 12, lines 7-11). Such description is consistent with the surface markings shown on the liner material 75 in Fig. 5E, i.e., a woven material.

Thus, Cox describes a plurality diamond shaped elements being sewn onto a single strip of woven material. Further, Cox clearly fails to teach or suggest that its diamond shaped elements 73 may be sewn between two of its woven strips.

Moreover, Cox teaches that a stent or a stent-graft may also include strips of PTFE disposed over the stent. (See, Cox, Figure 5D). More specifically, Cox describes the strips of PTFE as being "a ribbed PTFE liner". (Cox, column 12, lines 16-18). Cox, however, fails to teach or suggest that the diamond shaped elements 73 or any other stent embodiments may be sewn onto or otherwise attached to such PTFE strips prior to the helical winding of such strips to form a tubular device. Thus, Cox recognized that stent-grafts may contain strips of PTFE, but Cox failed to teach or suggest that such PTFE strips may have stent wires sewn or otherwise attached thereon, especially in a planar fashion prior to helical winding.

Further, in other embodiments, Cox fails to teach that other stent-grafts may be formed by helically winding planar stent-graft assemblies or are made from non-woven liners. In these other embodiments where Cox is silent on the particular construction details of its liner or graft materials, i.e., not specifically describing the graft yarns as being woven or ribbed PTFE, Cox specifically teaches that its stent-grafts are formed from cylindrical grafts with cylindrical

reinforcing elements being axially attached thereon. (See e.g., Cox, column 13, lines 6-26). Therefore, in its other embodiments Cox not only fails to teach or suggest the present invention, but teaches away from the present invention as specifically teaching the use of tubular stent and/or graft components as contrasted from planar stent-graft assembly strips.

Nolting:

While not admitting that Nolting is prior art to the present invention, nevertheless Nolting also fails to teach or suggest the present invention. Nolting is directed to a stent graft, particularly one made from ePTFE tape. Nolting forms the stent graft as follows:

Specifically, a first tape is wrapped about the mandrel. Next, the stent is loaded onto the mandrel over the first tape. A second tape is then wrapped over the stent. (Nolting, column 8, lines 49-54)

Thus, Nolting teaches that grafts having a stent embedded between layers of ePTFE are to be formed by first winding ePTFE tape onto a mandrel, followed by loading a stent there over, and then wrapping additional ePTFE tape.

Shull:

While not admitting that Shull is prior art to the present invention, nevertheless Shull also fails to teach or suggest the present invention. Shull is directed a stent-graft. A tubular graft is made from helically winding ePTFE tape. The tubular ePTFE graft is then placed over a tubular stent to form the stent-graft. The method is quite complicated as the graft must be first made, then removed from a mandrel, and then positioned over a stent, as follows:

The method of manufacturing the assembly according to a first embodiment of the present invention comprises helically wrapping a polymeric tape around a mandrel. The tape is wrapped at a particular angle to the perpendicular axis of the mandrel in order to achieve the desired distensibility of the membrane. The method further comprises sintering the tape to itself over the mandrel under particular parameters to produce a thin tube with desired radial distensibility;

removing the thin tube from the mandrel; covering the stent with the thin tube; suturing the graft to the stent; and invertedly folding the ends of the graft over the ends of the stent. (Shull, column 5, lines 24-34) (emphasis added)

Thus, Shull teaches that grafts formed from ePTFE tape are to be formed by winding the tape onto a mandrel, followed by loading a stent there over. Further, Shull teaches that its tubularly formed ePTFE graft is to be placed over the stent exterior and that stent interior, except for portions immediately proximal to the terminal ends, are not covered with the ePTFE graft material. (See, Fig. 7)

Schmitt:

Schmitt teaches that a textile graft having a liner may be formed by winding tape material over a mandrel and positioning a tubular textile graft there over, as follows:

A composite soft-tissue prosthesis formed in accordance with the present invention may be made by first choosing a mandrel with an outside diameter corresponding to an inside diameter of a natural body lumen which is to be replaced. The mandrel preferably has a smooth outer surface. The liner may be produced from expanded PTFE film or other suitable polymer, which has been slit into a narrow tape (3-10 mm). The expanded PTFE tape is wound onto the smooth mandrel to form the liner. The textile substrate is made having an inner diameter close to the outer diameter of the expanded PTFE liner and is positioned over the liner while the liner is still on the mandrel. The entire assembly may be placed into an oven at a sufficiently high temperature to fuse the textile substrate to the polymeric liner. (Schmitt, column 7, lines 27-39) (emphasis added)

Alternatively, Schmitt teaches that the liner need not be made of tape, as follows:

An alternative method of making the composite soft-tissue prosthesis formed in accordance with the present invention includes forming a thin wall tubular liner by extruding a polymer. A textile substrate is made having an inner diameter close to the outer diameter of the polymeric

liner. The textile sleeve is passed over the liner and heat conditioned to fuse the liner within the textile substrate.

Yet another method of forming the composite soft-tissue prosthesis formed in accordance with the present invention includes dip-casting a polyurethane resin onto a mandrel to form the liner. The textile substrate is dimensioned to be passed over the dip-casted polyurethane liner. The composite structure is preferably heat conditioned to fuse the textile substrate to the polyurethane liner. (Schmitt, column 7, lines 49-63) (emphasis added)

Thus, Schmitt teaches that lined grafts may be formed from an ePTFE tape by winding the tape onto a mandrel or alternatively forming a tubular liner directly on a mandrel, followed by loading a textile graft there over.

Pinchuk '913:

Pinchuk '913 is directed to a method of making a stent from an undulating wire. A generally planar, undulating length of wire is helically wound over a cylindrical mandrel to form the stent. (Pinchuk '913, column 5, lines 37-55).

Pinchuk '913, however, fails to teach or suggest the use of a graft with its stent.

Pinchuk '958:

Pinchuk '958 is directed to a method of making a stent from an undulating, carbon-coated wire. A generally planar, undulating length of wire is helically wound over a cylindrical mandrel to form a carbon-coated stent. (Pinchuk '958, column 5, lines 8-33).

Pinchuk '958, however, fails to teach or suggest the use of a graft with its stent.

Pinchuk '877:

Pinchuk '877 is directed to a method of making a stent from an undulating wire. A generally planar, undulating length of wire is helically wound over a cylindrical mandrel to form the stent. (Pinchuk '877, column 5, lines 18-54).

Pinchuk '877, however, fails to teach or suggest the use of a graft with its stent.

Shannon:

The Examiner cites Shannon for its teachings that a stent component may be disposed between two PTFE graft components.

Shannon, however, teaches that its tubular liner 12 must be first placed on a tubular mandrel 50, a tubular stent 14 is then disposed over the liner 12, and then the outer cover is disposed over the stent 14 by helically wrapping a tape 17 over the stent. (Shannon, column 10, line 50, to column 11, lines 13; and Figs. 4b-4f). The liner 12 is described as being formed by extruding PTFE through a tubular extrusion die. (Shannon, column 7, lines 32-35). The tape 17 is described as being formed by extruding PTFE through a film extrusion die. (Shannon, column 8, lines 13-17). Further, the stent is a braided stent having overlapping stent wires. (See e.g., Figs. 2 and 4c).

Thus, Shannon teaches at most a PTFE stent-graft is formed from an extruded tubular PTFE graft and a tubular stent, both of which are disposed over a tubular mandrel, followed by helically wrapping an extruded PTFE tape. Such teachings, however, are in direct contrast to the claimed recitations of the present invention.

Brauker:

The Examiner cites Brauker for its teachings that a stent component may be disposed between two PTFE graft components.

While not admitting that Brauker is prior art to the present invention, nevertheless Brauker also fails to teach or suggest the present invention. Brauker forms its graft components by wrapping ePTFE graft material onto a mandrel (Brauker, column 9, line 66, to column 10, line 1; and column 10, lines 59-66) or by extruding tubular ePTFE onto a mandrel (Brauker, column 13, lines 13-47). Thus, Brauker forms a tubular ePTFE graft. A stent 80 is shown as having an inner liner of such tubular-formed graft, an outer cover of such tubular-formed graft, or both.

Brauker, therefore, fails to teach or suggest the formation of a planar strip of stent-graft material as set forth in the present invention.

Martin:

The Examiner cites Martin for its teachings that a stent may be made from nitinol and may have an undulated configuration.

Martin, however, specifically teaches that an undulating stent wire is to be helically wound around a mandrel to form its tubular stent. (Martin, column 13, lines 9-12). Graft material is also placed over a mandrel to form an inner tubular liner. (Martin, column 14, lines 4-6). The tubular stent removed from its mandrel and is then positioned over the inner liner, which is disposed over its mandrel, to form a stent-graft. (Martin, column 14, lines 8-10). A flat ribbon PTFE is then wrapped around the exterior surface of the stent. (Martin, column 14, lines 13-17).

Thus, Martin forms its prosthesis by individually placing different components of the prosthesis over a mandrel. Accordingly, Martin fails to teach or suggest the formation of an essentially flat, planar strip of stent-graft material as set forth in the present invention.

Section 103 Rejections:
Applicable Law

In establishing a *prima facie* case of obviousness, the cited references must be considered for the entirety of their teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). Further, it is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection. *Id.* Thus, the express teachings of Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958, Pinchuk '877, Shannon, Brauker and Martin, which would lead one away from the methods of the present invention, may not be ignored during examination.

Further, it is incumbent upon the Examiner to provide a reason why one of ordinary skill in the art would have been led to modify a prior art document or to combine documents to arrive at the claimed invention. The requisite motivation for relying upon the cited references and making the proposed combination must reference some teaching, suggestion or inference in the prior art as a whole, or from the knowledge generally available to one of ordinary skill in the art and not from Applicants' disclosure. *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992).

Moreover, it is well established that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness and any attempt at hindsight reconstruction using Appellants' disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

TRAVERSAL OF THE SECTION 103 REJECTIONS:

Independent Claims 1, 8 and 17 Are Patentably Distinct Over Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958 and Pinchuk '877

As discussed above, Cox fails to teach or suggest forming an essentially flat, planar assembly strip by, *inter alia*, forming the assembly strip comprising first and second planar

graft strips of extruded, cast or molded polymeric graft material and a planar stent wire, stent or stent material positioned between the planar graft strips. Cox describes the positioning of wires onto a surface of a graft strip, in particular Cox's textile or woven graft strip. While Applicant does not agree with the broad reading of Cox as suggested by the Examiner relating to construction of its graft strip, i.e., Examiner's assertion that Cox's teaching is not limited to PTFE yarns, such a broad reading of Cox still does not render the present claims obvious in combination with any of the cited references. Please note that the Applicant does hereby preserve the right to traverse the Examiner's broad reading of Cox relating to PTFE construction, but is not presenting further argument to the same as the claimed invention is clearly patentable over the cited references regardless the construction of Cox's graft.

As Cox fails to teach or suggest a planar stent being positioned between planar graft strips, the Action must use secondary references at attempting to present a *prima facie case* of obviousness. The secondary references, however, all require that stent-grafts having non-textile graft portions be formed by methods in direct contrast to the methods of the present invention, i.e. teach away from the present invention, as follows:

- (i) Nolting teaches the ePTFE tape is first wrapped about a mandrel, and then a stent is loaded over the wrapped tape. (Nolting, column 8, lines 49-54);
- (ii) Shull wraps ePTFE tape around a mandrel and forms a tubular ePTFE graft there over. The ePTFE graft is removed from the mandrel. The ePTFE graft is then positioned over a tubular stent to form a stent-graft. (Shull, column 5, lines 23-34);
- (iii) Schmitt teaches that a tubular liner is first formed on a mandrel either by wrapping ePTFE tape or by extrusion. A textile graft is passed over the liner to form a lined textile graft. (Schmitt, column 7, lines 27-63); and
- (iv) Pinchuk '913, Pinchuk '958 and Pinchuk '877 teach that a stent may be formed by helically wrapping an undulating wire, but fail to teach or suggest the use of a graft with the stent or a method for making a stent-graft. (Pinchuk '913, column 5, lines 37-55; Pinchuk '958, column 5, lines 8-33; Pinchuk '877, column 5, lines 18-54).

As Cox fails to teach or suggest a method of forming a tubular stent-graft by, *inter alia*, forming a planar assembly strip comprising of a planar stent positioned between two planar graft strips and winding the assembly, there must be some teaching or suggestion in the secondary references to cure the deficiencies of Cox. While the Examiner previously ignored the express teaching of the secondary references that teach away from the present invention under the rationale that the secondary references were not being cited for processing steps, but only being cited for materials of construction of the graft component, such divergent and contrary teachings may not be ignored.

The only teachings of a stent being positioned between two graft layers are the secondary references. All of the secondary references that teach a stent being positioned between two graft layers, however, they specifically teach away from the methods of the present invention. The step or steps of, *inter alia*, positioning a planar stent between first and second planar graft strips are no longer merely an issue of material of construction of the graft strips, but are method or process steps or considerations. Accordingly, the Examiner's assertion that one may ignore the divergent and contrary processing steps and requirements of the secondary references for a *prima facie* case of obviousness is now clearly without merit and is further clearly contrary to accepted law because the Examiner must use the teachings from the secondary references on how to apply a stent between two graft layers.

Such express teachings of Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958 and Pinchuk '877, which would lead one away from the methods of the present invention, may not be ignored during examination. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). Further, the Examiner is prohibited against ignoring such contradictions while only picking portions that support the alleged rejections. *Id.*

Thus, the only teaching of forming an essentially flat, planar stent-graft assembly comprising first and second essentially flat, planar graft strips and an essentially flat, planar stent positioned therebetween is Applicant's own specification, and any hindsight reconstruction of the cited references to present a *prima facie* case of obviousness is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Thus, Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958 and Pinchuk '877, individually or in any combination, fail to teach or suggest the present invention as presently defined in independent claims 1, 8 and 17. Reconsideration and withdrawal of the rejections of independent claims 1, 8 and 17, and all claims dependent therefrom, are therefore respectfully requested.

Independent Claims 1, 8 and 17 Are Patentably Distinct Over Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958, Pinchuk '877, Shannon and Brauker

As discussed above, Cox fails to teach or suggest forming an essentially flat, planar assembly strip by, *inter alia*, forming the assembly strip comprising first and second planar graft strips of extruded, cast or molded polymeric graft material and a planar stent wire, stent or stent material positioned between the planar graft strips. As discussed above, the secondary references (i.e., Nolting, Shull or Schmitt) specifically teach the helical winding of PTFE tape to produce a tubular graft over a mandrel or a stent fail, and the tertiary references (i.e., Pinchuk '913, Pinchuk '958 and Pinchuk '877) fail to teach or suggest the use of graft strips with a stent. The quaternary references (i.e., Shannon and Brauker), however, also all require that stent-grafts having non-textile graft portions be formed by methods in direct contrast to the methods of the present invention, i.e. teach away from the present invention, as follows:

(i) Shannon teaches that a tubular liner must be first placed on a tubular mandrel, a tubular stent is then disposed over the liner, and then the outer cover is disposed over the stent

by helically wrapping a tape over the stent (Shannon, column 10, line 50, to column 11, lines 13; and Figs. 4b-4f); and

(ii) Brauker forms its graft by wrapping graft material onto a mandrel or by extruding a tubular graft onto a mandrel (Brauker, column 9, line 66, to column 10, line 1; column 10, lines 59-66; column 13, lines 13-47).

While the Examiner previously ignored the express teaching of the quaternary references that teach away from the present invention under the rationale that the quaternary references were not being cited for processing steps, but only being cited for materials of construction of the graft component, such divergent and contrary teachings may not be ignored as Cox, alone or in combination with the secondary and/or tertiary references, fail to teach or suggest the methods of the present invention as presently defined in the independent claims..

As such, the express teachings of Shannon and Brauker, which would lead one away from the methods of the present invention, may not be ignored during examination. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). Further, the Examiner is prohibited against ignoring such contradictions while only picking portions that support the alleged rejections. *Id.*

Thus, the only teaching of forming an essentially flat, planar stent-graft assembly comprising first and second essentially flat, planar graft strips and an essentially flat, planar stent positioned therebetween is Applicant's own specification, and any hindsight reconstruction of the cited references to present a *prima facie* case of obviousness is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Thus, Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958, Pinchuk '877, Shannon and Brauker, individually or in any combination, fail to teach or suggest the present

invention as presently defined in independent claims 1, 8 and 17. Reconsideration and withdrawal of the rejections of claims 1-9, 11-24 and 26 are therefore respectfully requested.

Claim 25 Is Patentably Distinct Over Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958, Pinchuk '877 and Martin

The action cited Martin for its teachings of an elongate undulating nitinol stent wire.

While Martin discloses an elongate undulating nitinol stent, none of the stent-grafts disclosed therein are produced in accordance with claimed recitations of the subject application. For example, Martin forms its stent-graft by placing graft material over a mandrel; winding a stent wire around a mandrel to form its tubular stent, and wrapping a flat PTFE ribbon around the exterior surface of the stent. (Martin, column 13, lines 9-12; column 14, lines 4-17).

Thus, Martin fails to cure the deficiencies of Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958 and Pinchuk '877. Additionally, the teaching of Martin and the teachings of the other cited references directed to the helical winding of ePTFE tapes to form a graft without having stent or wire components thereon before any helical winding may not be ignored by the Examiner. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). Further, the Examiner is prohibited against ignoring such contradictions while only picking portions that support the alleged rejections. *Id.*

Thus, the only teaching of forming a stent-graft assembly comprising an essentially flat, planar graft strip of extruded, cast or molded polymeric material and an essentially flat, planar stent is Applicant's own specification and any hindsight reconstruction of the cited references to present a *prima facie* case of obviousness is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Thus, Cox, Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958, Pinchuk '877 and Martin, individually or in any combination, fail to teach or suggest the present invention as presently defined in claim 25.

Therefore, reconsideration and withdrawal of the rejection of claim 25 are respectfully requested.

Conclusion

In conclusion, none of the cited references, individually or in combination, teach or suggest the present invention. Further, entry of the amendments may not properly be ignored as being new consideration or requiring further consideration as no new claim limitations are being offered. If, however, the Examiner deems that reconsideration is necessary, then the finality of the Action should be withdrawn as the Examiner has improperly ignored the express teaching of the secondary, tertiary and quaternary references that specifically teach away from the present invention.

Summary

Therefore, Applicant respectfully submits that independent claims 1, 8 and 17, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

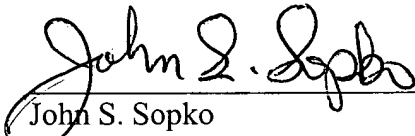
Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if

Application No.: 10/057,667
Amendment and Response dated April 7, 2005
Reply to Final Office Action of February 15, 2005
Docket No.: 760-12 DIV/RCE
Page 26

any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,



John S. Sopko
Registration No.: 41,321
Attorney for Applicants

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700